Atty. Dkt. No. 078728-0104

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Natarajan SETHURAMAN et al.

Title: PEGYLATION OF THERAPEUTIC

**AGENTS** 

Appl. No.: 09/972,245

FEB 0 3 2003

Filing Date:

g 10/09/2001

Examiner: Not yet assigned

Art Unit: 1645

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR § 1.56

Commissioner for Patents Box PATENT APPLICATION Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

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## **RELEVANCE OF EACH DOCUMENT**

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All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Date January 31, 2003

**FOLEY & LARDNER** 

Customer Number: 22428

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PATENT TRADEMARK OFFICE

Telephone: (202) 672-5404 Facsimile: (202) 672-5399 Respectfully submitted,

Stephen A. Bent

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PTO/SB/08 (08-00

Approved for use through 10/31/2002. OMB 0651-003

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

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JAN 3	1 2003 ATATEMEN	IT BY APPLIC	ANT	Filing Date	10/09/2001	
-	te Submitte	ed: January 31	2003	First Named Inventor	Natarajan SETHURAMAN	
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TRADE USE as many sheets as no			essary)	Examiner Name	Not yet assigned	
Call	eet 1	of	1	Attorney Docket Number	078728-0104	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Number	U.S. Patent Document    Kind   Name of Patentee or Applicant	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A1	5,880,255		DELGADO et al.	03/09/1999	RECEIVED	
						FEB 0 3 2003	
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	For Office <sup>3</sup>	eign Patent [ Number <sup>4</sup>	Oocument Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т6
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>		
	A2	HOLCENBERG et al. "Biologic and Physical Properties of Succinylated and Glycosylated Acinetobacter Glutaminase-Asparaginase"; The Journal of Biological Chemistry, Vol. 250, No. 11, 6/75, pp. 4165-4170.			
	А3	FUERTGES et al. "The Clinical Efficacy of Poly(Ethylene Glycol)-Modified Proteins", Journal of Controlled Release, 12 (1990) January , No. 1/3, Amsterdam, NL, pp. 139-148.			
	A4	KAFKEWITZ et al., "Enzyme-induced asparagine and glutamine depletion and immune system function", The American Journal of Clinical Nutrition 37: June 1983, pp. 1025-1030			

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.